DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 9, 2015

Hangzhou Jinlin Medical Appliances Co., Ltd.
c/o Mr. Mike Gu
Regulatory Affairs Manager
OSMUNDA Medical Device Consulting Co., Ltd
No.9, 16th Ave. Hangzhou Economic and Technological
Development Zone, Hangzhou, Zhejiang Province
310018, CHINA

Re: K142764
Trade/Device Name: KYOLING CPR Mask with Oxygen Port,
KYOLING CPR Mask without Oxygen Port
Regulation Number: 21 CFR 868.5870
Regulation Name: Non-Rebreathing Valve
Regulatory Class: II
Product Code: CBP
Dated: June 1, 2015
Received: June 8, 2015

Dear Mr. Gu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K142764

Device Name
KYOLING CPR Mask With Oxygen Port

Indications for Use *(Describe)*
The CPR Mask with Oxygen Port is designed to assist in providing immediate life support (mouth to mask ventilation) to health emergency victims requiring oxygen support (inhalation) or cardiopulmonary resuscitation (CPR) rescue techniques. The CPR Mask with Oxygen Port is for prescription use.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K142764

Device Name
KYOLING CPR Mask Without Oxygen Port

Indications for Use *(Describe)*
The CPR Mask without Oxygen Port is designed to assist in providing immediate life support (mouth to mask ventilation) to health emergency victims requiring cardiopulmonary resuscitation (CPR) rescue techniques. The resuscitator without oxygen port is for over-the-counter use.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

I. SUBMITTER

Hangzhou Jinlin Medical Appliances Co., Ltd.

No.9, 16th Ave. Hangzhou Economic and Technological

Development Zone, 310018, Hangzhou, Zhejiang Province, China

Phone: +86-571-86911905

Fax: +86-571-86840897

Primary Contact Person: Mike Gu

Regulatory Affairs Manager

OSMUNDA Medical Device Consulting Co., Ltd

Tel: (+86) 20-6232 1333

Fax: (+86) 20-8633 0253

Secondary Contact Person: Ms. Lydia HE

Hangzhou Jinlin Medical Appliances Co., Ltd

Date Prepared: June 01, 2015

II. DEVICE

Device trade name: KYOLING CPR Mask With Oxygen Port(Prescription Use)

KYOLING CPR Mask Without Oxygen Port(OTC Use)

Common/Usual Name: Emergency CPR Mask

Classification Names Valve, Non-Rebreathing

Regulation classification: 21 CFR 868.5870

Panel: Anesthesiology

Regulation Class: II

Product Code: CBP

III. PREDICATE DEVICE Prescription Use:

Brand MedSource CPR Mask, MedSource International, LLC, K081516

OTC Use:

Genuine First Aid CPR Face Mask without oxygen port,, Genuine First Aid LLC, K112126

These predicates have not been subject to a design-related recall.

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

The KYOLING CPR mask is used during cardiopulmonary resuscitation procedures, which are used in emergency situations to supply oxygen and produce blood flow in the heart and lungs.

The CPR mask is made of PVC and one-way valve made of medical grade K-resin, the mask is used for mouth-to-mask breathing, it provides a physical barrier between the rescuer and victim, eliminating direct contact of the rescuer's lips with the unknown subject; and also it promotes an airtight seal to the face allowing ventilation through both the mouth and nose simultaneously. The KYOLING CPR Mask includes transparent dome, universal breathing tube, one-way filtered valve, head strap, and with Oxygen Port or without Oxygen Port.

Specification

CPR Mask with Oxygen Port: The physical size for the device is 99.5mm in height* 122mm in length;

- Inspiratory resistance: <5 cmH_2O (at 50 L/min);
- Expiratory resistance: <5 cmH_2O (at 50 L/min)

CPR Mask without Oxygen Port: The physical size for the device is 99.5mm in height * 122mm in length;

- Inspiratory resistance: <5 cmH_2O (at 50 L/min);
- Expiratory resistance: <5 cmH_2O (at 50 L/min)

V. INDICATIONS FOR USE

The CPR Mask with Oxygen Port is designed to assist in providing immediate life support (mouth to mask ventilation) to health emergency victims requiring oxygen support (inhalation) or cardiopulmonary resuscitation (CPR) rescue techniques. The CPR Mask with Oxygen Port is for prescription use.

The CPR Mask without Oxygen Port is designed to assist in providing immediate life support (mouth to mask ventilation) to health emergency victims requiring cardiopulmonary resuscitation (CPR) rescue techniques. The resuscitator without oxygen port is for over-the-counter use.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The sponsor identified the similarities and differences of the proposed CPR MASK device to the legally marketed predicate MedSource CPR Mask K081516 to which substantial equivalency is claimed.

Specification	Predicate Device	Proposed Device
Manufacturer	MedSource International, LLC	Hangzhou Jinlin Medical Appliances Co., Ltd
Device name	MedSource (Brand) CPR Mask	KYOLING CPR Mask With Oxygen Port(Prescription Use)
K number	K081516	--
Indications for Use	The MedSource CPR Mask is designed to assist in providing immediate life support (mouth to mask ventilation) to health emergency victims requiring oxygen support (inhalation) or cardiopulmonary resuscitation (CPR) rescue techniques.	The CPR Mask with Oxygen Port is designed to assist in providing immediate life support (mouth to mask ventilation) to health emergency victims requiring oxygen support (inhalation) or cardiopulmonary resuscitation (CPR) rescue techniques. The CPR Mask with Oxygen Port is for prescription use.
Inspiratory Resistance	2.84-2.87 cmH_2O	3.09-3.17 cmH_2O
Expiratory Resistance	2.96-3.01 cmH_2O	3.21-3.26 cmH_2O
Raw materials	CPR one-way valve: PVC/Silicon valve Face Mask: PVC Strap: Non-Woven	CPR one-way valve: Silicon Face Mask: PVC Strap: Non-Woven
Dimensions	Length: 100±3mm Width: 82±3mm	

Standards	ISO 5356-1:2004 Anaesthetic and respiratory equipment -- Conical connectors -- Part 1: Cones and sockets; AS 4259-1995 Ancillary devices for expired air resuscitation; ISO 10993-5:2009 Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity; ISO 10993-10:2010 Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization

Though the Inspiratory Resistance and Expiratory Resistance are slightly different, both the subject and predicate device meet the requirements for AS-4259-1995 Standard.

The sponsor identified the similarities and differences of the proposed CPR MASK device to the legally marketed predicate Genuine First Aid LLC K112126 to which substantial equivalency is claimed.

Specification	Predicate Device	Proposed Device
Manufacturer	Genuine First Aid LLC	Hangzhou Jinlin Medical Appliances Co., Ltd
Device name	Genuine First Aid CPR Face Mask without oxygen port	KYOLING CPR Mask Without Oxygen Port(Over-the-Counter Use)
K number	K112126	--
Indications for Use	The CPR mask (without oxygen port) is single use designed for mouth to mask ventilation to health emergency victims requiring cardiopulmonary resuscitation (CPR) rescue techniques of a nonbreathing adult. It is also used as a barrier that will direct expired air from the patient away from the user.	The CPR Mask without Oxygen Port is designed to assist in providing immediate life support (mouth to mask ventilation) to health emergency victims requiring cardiopulmonary resuscitation (CPR) rescue techniques. The resuscitator without oxygen port is for over-the-counter use.
Inspiratory Resistance	1.94@50L/min	3.09-3.17 cmH_2O
Expiratory Resistance	2.04@50L/min	3.21-3.26 cmH_2O
Raw materials	CPR one-way valve: K-Resin, Silicone Face Mask: PVC Strap: Non-Woven	CPR one-way valve: Silicon Face Mask: PVC Strap: Non-Woven
Dimensions	Length: 100±3mm Width: 82±3mm	

Standards	ISO 5356-1:2004 Anaesthetic and respiratory equipment -- Conical connectors -- Part 1: Cones and sockets; AS 4259-1995 Ancillary devices for expired air resuscitation; ISO 10993-5:2009 Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity; ISO 10993-10:2010 Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization

Though the Inspiratory Resistance and Expiratory Resistance are slightly different, both the subject and predicate device meet the requirements for AS-4259-1995 Standard.

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing:

The biocompatibility evaluation for the KYOLING CPR Mask was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The battery of testing included the following tests:

- ISO 10993-5: 2009-Cytotoxicity
- ISO 10993-10: 2010-Sensitization
- ISO 10993-10: 2010-Irritation

The cushion and valve is considered surface contacting for duration of less than 24 hours.

Bench testing:

Expiratory resistance and inspiratory resistance testing was for Kyoling CPR mask with oxygen port done using the test methods described in AS-4259-1995 Ancillary Devices for Expired Air Resuscitations

Parameters	Standard	Proposed device
Inpiratory resistance	<5cmH_2O	3.19~3.24 cm H_2O

Expiratory resistance	<5cmH_2O	3.31~3.37cmH_2O

Expiratory resistance and inspiratory resistance testing was for Kyoling CPR mask without oxygen port done using the test methods described in AS-4259-1995 Ancillary Devices for Expired Air Resuscitations

Parameters	Standard	Proposed device
Inpiratory resistance	<5cmH_2O	3.19~3.24 cm H_2O
Expiratory resistance	<5cmH_2O	3.31~3.37cmH_2O

Animal and clinical study:

The subject of this premarket submission, KYOLING CPR Mask, does not require clinical studies to support substantial equivalence.

VIII. CONCLUSIONS

Hangzhou Jinlin Medical Appliances Co., Ltd considers the Kyoling CPR mask with oxygen port is as safe and effective as the predicate device. It has the same intended use, indications for use, technological characteristics, and principles of operation as those of the predicate device. The minor differences between the Kyoling CPR mask with oxygen port and its predicate device raise no new issues of safety or effectiveness. Thus, the Kyoling CPR mask with oxygen port is substantially equivalent to its predicate device.

Hangzhou Jinlin Medical Appliances Co., Ltd considers the Kyoling CPR mask without oxygen port is as safe and effective as the predicate device. It has the same intended use, indications for use, technological characteristics, and principles of operation as those of the predicate device. The minor differences between the Kyoling CPR mask without oxygen port and its predicate device raise no new issues of safety or effectiveness. Thus, the Kyoling CPR mask without oxygen port is substantially equivalent to its predicate device.